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TREATMENT PATTERNS AND OUTCOMES IN THE FRENCH COHORT OF PATIENTS WITH UNRESECTABLE STAGE III OR STAGE IV MELANOMA (MELODY STUDY): A RETROSPECTIVE LONGITUDINAL SURVEY

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OBJECTIVES: Melanoma is the first mortality cause by skin cancer. The more advanced stages prognosis is remaining poor. The MELODY study had as primary objectives to describe the disease characteristics, treatment modalities/outcomes, and resources use in patients with unresectable Stage III-Stage IV (UNRSIII-SIV) melanoma. **METHODS:** MELODY was a three-country (France, Italy, UK) longitudinal, retrospective, observational survey. In the French cohort, 10 expert dermatology departments had to register all melanomas seen between July 2005 and June 2006. The UNRSIII-SIV cases, with minimum 2-month follow-up, were extracted for detailed description of the disease characteristics, treatments (systemic, local, supportive care), and outcomes and resource use, until May 1, 2008 or death. **RESULTS:** In France, 1224 patients (pts) were registered, in which 278 UNRSIII-SIV cases were extracted. At initial diagnosis, 34/1224 pts (2.8%) were UNRSIII-SIV; 253 pts (91%) received systemic treatment, while 230 (91%) had a chemotherapy of any line. In first-line systemic (n = 249), 198 pts (80%) were treated outside clinical trials, in whom 119 (60%) were on dacarbazine (D) and 35 (18%) on fotemustine (F) monotherapy; complete/partial response was noted for 21 pts (11%), with 2.9-month median response duration, median of progression-free survival (PFS) was 2.8 months (2.6; 3.5). In second line, 159 pts (57%) were treated, in whom 139 (87%) outside of clinical trials, with 75 (54%) on F, and 16 (12%) on D; median PFS was 2.5 months (2.1; 3.9). In case of systemic treatment/supportive care, there was a median of 20 (11; 30) hospitalization days (13 [6; 22] days for first line systemic) and 3 [1; 6] outpatient visits (1.5 [1.0; 5.0] for first-line systemic). **CONCLUSIONS:** In the French cohort of MELODY, chemotherapy treatments gave modest results in terms of complete/partial response and PFS, at a high cost of resource use, highlighting the unmet medical need.

CANCER – Patient-Reported Outcomes Studies

PCN114

VISITING DOCTORS WITH MALIGNANT MELANOMA

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OBJECTIVES: The incidence of malignant melanoma has been continuously growing; however, early identification contributes significantly to its effective treatment. As a prerequisite, the individual needs to see a specialist soon after the recognition of the first symptoms. Therefore, the aim of our study is to disclose the factors and patient attitude behind seeing a specialist in case of skin deformation in order to establish the method for effective treatment. **METHODS:** Retrospective cross-sectional study was carried out among patients in four cities (n = 280) who had been diagnosed with malignant melanoma within 5 years. Besides sociodemographic data, the questionnaire focused on the awareness and knowledge of the patient regarding melanoma, on risk factors, the general attitude of seeing doctors, and that of delaying factors in respect of melanoma. Single and multiple logistic regression were used in statistical analysis. **RESULTS:** After the recognition of skin deformation, only half of the patients visit a doctor within 1 year. The increase of latency (seeing a specialist more than 3 months after the incidence of the first symptoms) was four to seven times more frequent among those who demonstrate anxiety and distress, feel exposed to doctors, lie in the sun without any control, lack awareness of the disease, and have a lower rate of social support ($P < 0.01$). The study also revealed the shortages of primary care (e.g., insufficient examination, lack of information supply). Seeing a specialist in most of the cases was motivated by external factors. **CONCLUSIONS:** To estimate the benefit of developing programs focusing on health behavior and awareness building of the prevalence and incidence of malignant melanoma instead of facilitating several preventive interventional projects based on the screening of the population.

PCN115

EVALUATION OF SUPPORT SERVICES TO COLORECTAL CANCER PATIENTS IN MEXICO

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OBJECTIVES: To identify the association of sociodemographic, resource use, and adverse events variables with adherence to measure the return on investment of a patient education service for colorectal cancer patients taking capecitabine. **METHODS:** This was a prospective intervention of government patients in the country of Mexico of any age, with colorectal cancer and capecitabine treatment. The intervention group had access to a hot line, booklets, nutritional and psychological support; control group patients did not. a structured ad-hoc questionnaire applied the Morisky–Green Test to determine adherence to therapy via follow-up phone calls. Associations between variables and adherence between intervention group and controls were assessed using chi-square test. Emergency rooms (ER) visits were the economic indicator to establish cost differences between groups. Power analysis was conducted using PS Power and Sample Size Calculations version 3.0, January 2009. **RESULTS:** A total of 220 patients were included in this study (mean age 58.4 [26 to 89] years), 121 intervention patients (48 responded to first call; 70% adherence) and 99 control patients (30 responded to first call; 57% adherence). If the true odds ratio for adherence in intervention relative to control is 1.86, a power analysis projects statistical significance with 290 intervention patients and 181 controls to reject the null hypothesis with a probability (power) of 0.8. The reason for nonadherence "Does not know administration regime" did show statistical significance ($P = 0.019$) between the intervention (10% n = 2) and control group (47% n = 7). For ER visits related to adverse events, the control group rate was 13.33% (n = 4) versus 2.32% (n = 1) in the intervention group ($P = 0.067$). The cost for ER/day is $Mex 1,144.44 (USD 86.82). **CONCLUSIONS:** These preliminary results indicate that patients who receive intervention services may have improved adherence to medication and therefore fewer ER visits and costs. Continued enrollment will be able to determine true significance.

PCN116

ANALYSIS OF THE EQ-5D QUESTIONNAIRE FOR PATIENTS WITH ADVANCED HER2-POSITIVE GASTRIC CANCER (HER2+ AGC) BASED ON THE TRASTUZUMAB FOR GASTRIC CANCER (TOGA) STUDY

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OBJECTIVES: In the ToGA study, patients with HER2+ aGC (n = 584) who received trastuzumab + chemotherapy achieved significantly improved overall survival compared to patients receiving chemotherapy alone (HR = 0.74 (95% CI 0.60; 0.91, $P = 0.0046$; van Cutsem et al. 2009). Since published utilities in gastric cancer are rare, we report results of the EQ-5D analysis from ToGA here, particularly the obtained utility for progression-free-survival (PFS). **METHODS:** The EQ-5D was provided to patients at baseline and every 3 weeks until disease progression. The questionnaire was completed by the patient prior to any study specific assessment or discussion with their study care provider. Patients' EQ-5D responses were scored using UK-tariffs, according to the guidelines of the EuroQol group. Only fully completed questionnaires were included. Mixed effects random slope models in SAS v8.2 were developed to estimate the health state utility. The intercept and day of assessment were incorporated as random effects. Covariance structures were assessed for goodness of fit using Akaike Information Criteria. Secondary analyses that included a treatment indicator were performed to explore a possible treatment effect. EQ-5D analysis of a patient subgroup (with tumors highly expressing the HER2-protein, i.e., IHC3+ or IHC2+ and FISH+, metastatic at screening, n = 431), was also conducted. **RESULTS:** The unstructured covariance matrix was found to be the best fit and resulted into a PFS-utility of 0.73 (95% CI: 0.71; 0.75). The treatment effect was not found to be significant ($P = 0.1542$); i.e., no difference between the two treatment regimens was identified. Results were confirmed for the subgroup. **CONCLUSIONS:** Although only HER2+ patients were included in ToGA, the obtained utility value is in line with other published PFS-utilities in aGC. Given the large patient numbers, 0.73 can be regarded as a robust estimate of a patient-reported outcome. Further studies in aGC should attempt to assess the utility in patients following disease progression.

PCN117

UTILITY ELICITATION STUDY IN THE UK GENERAL PUBLIC FOR LATE STAGE CHRONIC LYMPHOCYTIC LEUKEMIA

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OBJECTIVES: In the UK, chronic lymphocytic leukemia (CLL) makes up 40% of all leukemias in patients over 65 years. The objective of this UK-based study was to obtain societal preferences for "progression-free" and "progressive" stages of late-stage CLL, and selected treatment-related adverse events. **METHODS:** A utility study, using the time-trade off (TTO) method, was conducted in the UK with 110 members of the general public for a baseline disease state (before treatment), three primary disease states (progression-free survival [PFS] response, PFS non-response, and disease progression) and four adverse event (AE) substates (PFS response with thrombocytopenia, neutropenia or severe infection, and PFS non-response with severe infection). Disease state vignettes were developed using literature and validated by expert CLL clinicians. Face-to-face interviews were conducted by trained interviewers. The TTO scores were converted into a utility value for each disease state and disutilities were calculated for AEs. Visual analogue scale (VAS) scores were also obtained. **RESULTS:** All participants were included in the analysis. The mean utility scores from the TTO for the primary disease states were: baseline: 0.549; PFS response: 0.671; PFS nonresponse: 0.394; and progression: 0.294. The mean TTO utility (disutility) scores for the AEs were: PFS response with thrombocytopenia, neutropenia, or infection, 0.563 (–0.108), 0.508 (–0.163), 0.476 (–0.195), respectively; PFS nonresponse with infection, 0.333 (–0.061). The VAS results were in line with the TTO results. **CONCLUSIONS:**